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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638

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EXAMINER

TRUONG, LINH T

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,650	<b>Applicant(s)</b> ZHU ET AL.	
	<b>Examiner</b> Linh Truong	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 11-15, 19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/7/03; 5/24/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 5 is objected to because of the following informalities: the phrase "beyond a minimum distance" is vague. "A minimum distance" can suggest either 1mm or 1ft. Appropriate correction is suggested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammerslag '5,759,194 (IDS).

For claims 1-7, Hammerslag teaches a tissue closure device comprising: an elongate body with a first portion 80 and a second portion 270 having a lumen, each portions having a distal end; the second portion 270 cannot be moved distally relatively to the first portion distal end beyond the minimum distance and is arranged concentrically and rigidly around the first portion 80; a patch 88 releasably connected to the distal end of the first portion; wherein the second portion lumen distal opening is spaced from the patch. The two portions extend generally parallel to a longitudinal axis of the elongate body and the first portion has a lumen having a first lumen opening

through the distal end with the patch covering at least a portion of the lumen opening (fig. 11 and col. 14, lines 43-57).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerschlag in view of Wilk et al. '5,236,455.

For claims 8-9, Hammerschlag does not teach that the first lumen is connectable to source of vacuum capable of drawing a vacuum through the first lumen to hold the patch in place. Wilk et al. teaches a tissue patch applicator with a lumen 52 connected to a source of vacuum 56 for holding a patch 50 temporarily in place before application to a ruptured membrane (fig. 4 and col. 4, lines 43-56). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made that the first lumen of Hammerschlag is fully capable of connecting to a vacuum source for temporarily holding the patch in place prior to its application.

Art Unit: 3761

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 8-9; 3; 10; 16- 17; 18; 1 and 8-10; and 1,8-9, and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1; 2; 3; 11-12; 15; 22; and 26, respectively, of U.S. Patent No. 6,589,269. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are merely broader than the claims in the patent.

Claim 1 of the patent "anticipates" application claims 1 and 8-9. Accordingly, application claims 1 and 8-9 are not patentably distinct from patent claim 1. Here patent claim 1 requires: a) an inner and outer lumen, b) a connector being connectable to a source of vacuum capable of drawing a vacuum through the inner lumen, c) a patch, d) the inner lumen being adapted to engage the patch, e) a space between the outer lumen distal opening and the patch, **and f) two connectors providing access to the inner and outer lumens**, respectively, while application claims 1 and 8-9 only requires:

Art Unit: 3761

a) an inner (first portion) and outer lumen (second portion), a patch (wound closure), b) a connector being connectable to a source of vacuum capable of drawing a vacuum through the inner lumen, c) a patch (wound closure), d) the inner lumen being adapted to engage the patch, and e) a space between the outer lumen distal opening and the patch.

Claims 2 and 3 of the patent are worded exactly as application claims 3 and 10.

Claims 11-12 of the patent "anticipates" application claims 16-17. Accordingly, application claims 16-17 are not patentably distinct from patent claims 11-12. Here patent claims 11-12 require: a tissue closure device in combination with an organ stabilizer adapted to be attachable to the tissue device, the organ stabilizer includes: 1) an elongate tube including a lumen, **2) a vacuum connection port, and 3) a suction port** adapted to be engagable with body tissue to secure the tissue in place with the vacuum while application claims 16-17 only require: a) an organ stabilizer adapted to be attachable to the tissue device, the organ stabilizer includes: 1) an elongate tube including a lumen having a distal opening connectable to a source of vacuum adapted to be engagable with body tissue to secure the tissue in place with the vacuum.

Claim 15 of the patent "anticipates" application claim 18. Accordingly, application claim 18 is not patentably distinct from patent 15. Both claims require the organ stabilizer device to have a ridge to maintain the placement of the tissue closure.

Claim 22 of the patent "anticipates" application claims 1 and 8-10. Accordingly, application claims 1 and 8-10 are not patentably distinct from patent claims 22. Here patent claim 22 requires: a) an inner and outer lumen, b) a connector being

Art Unit: 3761

connectable to a source of vacuum capable of drawing a vacuum through the inner lumen, c) a patch, d) the inner lumen being adapted to engage the patch, e) a space between the outer lumen distal opening and the patch, f) a release rod, **and g) two connectors providing access to the inner and outer lumens**, respectively, while application claims 1 and 8-10 only require: a) an inner (first portion) and outer lumen (second portion), a patch (wound closure), b) a connector being connectable to a source of vacuum capable of drawing a vacuum through the inner lumen, c) a patch (wound closure), d) the inner lumen being adapted to engage the patch, and e) a space between the outer lumen distal opening and the patch, and f) a release rod.

Claim 26 of the patent "anticipates" application claims 1, 8-9, and 17.

Accordingly, application claims 1, 8-9, and 17 are not patentably distinct from patent claim 26. Here patent claim 26 requires: a) an inner and outer lumen, b) a connector being connectable to a source of vacuum capable of drawing a vacuum through the inner lumen, c) a patch, d) the inner lumen being adapted to engage the patch, e) a space between the outer lumen distal opening and the patch, f) a tissue closure device in combination with an organ stabilizer adapted to be attachable to the tissue device, the organ stabilizer includes: 1) an elongate tube including a lumen, **2) a vacuum connection port, and 3) a suction port** adapted to be engagable with body tissue to secure the tissue in place with the vacuum, **and g) two connectors providing access to the inner and outer lumens**, respectively, while application claims 1 and 8-9, and 17 only require: a) an inner (first portion) and outer lumen (second portion), a patch (wound closure), b) a connector being connectable to a source of vacuum capable of

Art Unit: 3761

drawing a vacuum through the inner lumen, c) a patch (wound closure), d) the inner lumen being adapted to engage the patch, and e) a space between the outer lumen distal opening and the patch, and f) an organ stabilizer adapted to be attachable to the tissue device, the organ stabilizer includes: 1) an elongate tube including a lumen having a distal opening connectable to a source of vacuum adapted to be engagable with body tissue to secure the tissue in place with the vacuum.

***Allowable Subject Matter***

Claims 11-15, and 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,810,884 discloses a tissue closure device with two separate portions with one portion holding a wound closure mechanism. US Patent 6,287,323 B1 discloses the same invention as the prior art used in the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974. The examiner can normally be reached on Mondays to Fridays from 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached at 703-308-1412. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong



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